

IN THE SPECIFICATION

Please amend the specification in accordance with the following request.

Beginning after the paragraph starting at page 26, line 6, please insert the following figure description.

FIG. 5 is a graph illustrating the environmental pH values after administration of the proton pump inhibiting agent/buffer formulation.

Please replace the paragraph at page 53, line 30 to page 53, line 16 with the following paragraph (deleted text indicated by strikethrough):

Of the 24 remaining patients, 18 were males and 6 females. Ages at implementation of PPI therapy ranged from 2 weeks of age to 9 years old. Median age at start of therapy was 26.5 months [mean of 37 mo.] Early on, reflux was usually documented by endoscopy and confirmed by pH probe. Eventually, pH probe was dropped and endoscopy was the sole method for documenting reflux, usually at the time of another surgery (most often T-tubes or adenoidectomy). Seven patients had pH probe confirmation of GERD, whereas 18 had endoscopic confirmation of reflux including all eight who had pH probing done (see Graphs 1 and 2 below). Reflux was diagnosed on endoscopy most commonly by cobblestoning of the tracheal wall, with laryngeal and pharyngeal cobblestoning as findings in a few patients. Six

patients had neither pH nor endoscopic documentation of GERD, but were tried on PPI therapy based on symptomatology alone.

Please replace the paragraph at page 54, lines 6-14 with the following paragraph (deleted text indicated by strikethrough):

Most patients had been treated in the past with medical therapy in the form of antibiotics, steroids, asthma medications and other diagnosis-appropriate therapies. In addition, nine of the patients had been on reflux therapy in the past, most commonly in the form of conservative therapy such as head of bed elevation 30°, avoidance of evening snacks, avoidance of caffeinated beverages as well as cisapride and ranitidine—(See Graph 3 below).

Please replace the paragraph at page 55, line 14 to page 56, line 2 with the following paragraph (deleted text indicated by strikethrough):

Patients were categorized based on review of clinic notes and chart review into general categories: (1) improved; (2) unchanged; (3) failed; and (4) inconclusive. Of 24 patients with sufficient data for follow up, 18 showed improvement in symptomatology upon commencement of PPI therapy [72%]. The seven who did not respond were analyzed and grouped. Three showed no change in symptomatology and clinical findings while

on therapy, one complained of worsening symptoms while on therapy, one patient had therapy as prophylaxis for surgery, and two stopped therapy just after its commencement—~~(see graph 4)~~. Setting aside the cases in which therapy was stopped before conclusions could be drawn and the case in which PPI therapy was for purely prophylactic reasons, leaves (17/21) 81% of patients that responded to Choco-Base suspension. This means that 19% (4/21) of patients received no apparent benefit from PPI therapy. Of all these patients, only 4% complained of worsening symptoms and the side effects were 4% (1/21) and were mild bloody stool that completely resolved upon cessation of therapy.

Please delete Graphs 1 – 4 appearing at page 60 of the specification as filed.